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EXAMINER

UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,701	Applicant(s) JANSSEN, CATHARINA PHILIPPINA	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-12, 19-26, 28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) 24, 25 and 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-12, 19-23, 26, 28, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

This Office Action is in response to the Applicant's reply received 12/01/10. Claims 1, 7-12, 19-26, 28, 30-37 are pending. Claims 24-25, and 30-35 are withdrawn. Claims 1, 7-12, 19-23, 26, 28, 36 and 37 are considered on the merits.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 7, 19-23 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Trau et al. (Biosensors and Bioelectronics, Available online 5/14/03) in support of definitions from Merriam-Webster.com ("battery" definition #4 and "electrolyte").

These claims are to a battery comprising:

- An electrolyte suspension comprising plurality of hollow particles;
- These hollow particles entrap and oxidase enzyme, specifically **glucose oxidase (GOX)**;
- These hollow particles comprise an outer shell that is electrically conductive and permeable to the enzyme substrate.

These claims have a series of intended uses as follows:

- The battery is for use in combination with a microchip;
- The electrolyte suspension can be used to generate a current of electrons.

These intended uses and do not impart a structural relationship, such as an additional component, to this composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these intended uses are afforded little patentable weight.

Also the term "battery" is not explicitly defined in the specification. While the Applicant appears to mean "battery" as the galvanic cell of figure 1, the common use of the term "battery" is far broader. Merriam Webster online defines battery in the electrical sense as "a combination of apparatus for producing a single electrical effect" or "a single cell that furnishes electric current". Therefore in the broadest but reasonable terms a battery is any apparatus or composition that generates an electric current or produces a single electrical effect. Claims reading on such an apparatus or composition will read on these claims.

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Trau et al. teach glucose oxidase entrapped in hollow particles with outer shells comprising polyelectrolytes (Fig 1, and Fig 2B) such as **polyallylamine-HCl (PAH)**, **poly-(sodium-4-styrenesulfonate) (PSS)** and **polyacrylic acid (PAA)** (pg 1493, Section 2.1). These particles are embedded in an electrically conductive matrix such as a platinum/carbon electrode or a gel-like membrane (Figs 2B and C and Fig 5). Trau et al. teach that these particles generate a current upon addition of glucose (Fig 7) and thus meet the broad definition of battery.

Since these materials are classified as electrolytes they are inherently electrically conductive as supported by Merriam Webster Online (“electrolyte”, Definition 1). Furthermore the outer shells of these hollow particles made from these polyelectrolytes inherently have conductivity and substrate permeability as indicated by the current generated when glucose is added to these hollow particles entrapping GOX (Fig 7). If these hollow particles were not inherently permeable to glucose then no current would be generated by the GOX for lack of substrate. If these hollow particles were not electrically conductive then they would insulate the GOX and prevent current flow. Both of these scenarios are unlikely given the substantial current flow over the control shown in Fig 7 that is a direct result of glucose addition.

Therefore the claims are anticipated by the above reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 7-12, 19-23, 28 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Trau et al., in view of Zaitsev et al. (Colloids and Surfaces A, available online May 2003) in further view of Vriezema et al. (Angew. Chem. Int. Ed. Available online, 2003).

These claims are to a battery comprising:

- An electrolyte suspension comprising plurality of hollow particles;
- These hollow particles entrap and oxidase enzyme, specifically **glucose oxidase (GOX)**;
- These hollow particles comprise an outer shell that is electrically conductive and permeable to the enzyme substrate;
- The hollow shells comprise PS-PIAT with thiophene side-chains attached;

As mentioned above, these claims have a series of intended uses as follows:

- The battery is for use in combination with a microchip;
- The electrolyte suspension can be used to generate a current of electrons.

These intended uses and do not impart a structural relationship, such as an additional component, to this composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these intended uses are afforded little patentable weight.

Also the term “battery” is not explicitly defined in the specification. While the Applicant appears to mean “battery” as the galvanic cell of figure 1, the common use of the term “battery” is far broader. Merriam Webster online defines battery in the electrical sense as “a combination of apparatus for producing a single electrical effect” or “a single cell that furnishes electric current”. Therefore in the broadest but reasonable terms a battery is any apparatus or composition that generates an electric current or produces a single electrical effect. Prior Art

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reading on such an apparatus or composition will read on these limitations. Also claim 28 contains the limitations that claim 1 is a nano-battery. However the specification does not give a specific definition or description on what makes the battery nano. Therefore in the interest of prosecution the limitation will be broadly interpreted as any component of the battery that encompasses a nanometer scale.

Trau et al. teach glucose oxidase entrapped in hollow particles with outer shells comprising polyelectrolytes (Fig 1, and Fig 2B) such as **polyallylamine-HCl (PAH)**, **poly-(sodium-4-styrenesulfonate) (PSS)** and **polyacrylic acid (PAA)** (pg 1493, Section 2.1) to increase enzyme stability (Trau, pg 1495, col 1). Trau et al. teach that these particles generate a current upon addition of glucose (Fig 7) and thus meet the broad definition of battery.

Since these materials are classified as electrolytes they are inherently electrically conductive as supported by Merriam Webster Online (“electrolyte”, Definition 1). Furthermore the outer shells of these hollow particles made from these polyelectrolytes inherently have conductivity and substrate permeability as indicated by the current generated when glucose is added to these hollow particles entrapping GOX (Fig 7). If these hollow particles were not inherently permeable to glucose then no current would be generated by the GOX for lack of substrate. If these hollow particles were not electrically conductive then they would insulate the GOX and prevent current flow. Both of these scenarios are unlikely given the substantial current flow over the control shown in Fig 7 that is a direct result of glucose addition. What Trau et al. does not teach is that the GOX is entrapped in hollow particles made from PS-PIAT. However this would have been obvious given the combined teachings of Zaitsev et al. and Vriezema et al.

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Like Trau et al., Zaitsev et al. teach that hollow particles made of the same polyelectrolyte, PSS (Zaitsev, sec 2.1), but instead of GOX they encapsulate the enzyme lipase while retaining its activity (Zaitsev, Abstract). Therefore it would have been obvious to one of ordinary skill in the art that both GOX and lipase are successfully encapsulated in electrically conductive hollow spheres under the same conditions. What Trau et al. and Zaitsev et al. do not teach is that the material to encapsulate is PS-PIAT with polythiophene sidechains. This is taught by Vriezema et al., who teach that electrically conductive hollow particles made from the block copolymer PS-PIAT (Fig 1 and 2) that encapsulates the lipase (pg 775, col 1) and are approximately 100 nm in diameter so read on the limitation of a nano-battery. Vriezema et al. teaches that the PS-PIAT particles are polymerized to the thiophene side-groups via the chemical oxidant BRP (pg 774, col 1). Vriezema et al. teaches that their encapsulation method enhances enzyme stability (Vriezema, pg 775, col 2).

It would have been obvious to one of ordinary skill in the art to replace the polyelectrolyte polymers of Trau et al. with the PS-PIAT of Vriezema et al. in the encapsulation of GOX. This is because Zaitsev et al. teaches that lipase and GOX are successfully encapsulated under the same conditions, therefore one of ordinary skill in the art would predict that since lipase was successfully encapsulated in PS-PIAT, then likewise so too would GOX. Furthermore both the polyelectrolyte capsule and the PS-PIAT capsule are electrically conductive and allow substrate to permeate through the shell (Zaitsev, pg 775, col 2). Both teach that their encapsulation methods enhance enzyme stability. Also both Trau et al. and Vriezema et al. refer to their enzyme entrapping capsules as "reactors" (Trau, Abstract; Vriezema, pg 775, col 1 and 2), therefore establishing that both are known for the same purpose. Therefore one of

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ordinary skill in the art would recognize that it would have been obvious to substitute the polyelectrolyte capsules in the battery of Trau et al. with the conductive PS-PAIT capsules of Vriezema et al. since they both are known to encapsulate enzymes, enhance enzyme stability and are conductive, so would have been predicted by one of ordinary skill in the art to function in the same matter since they have similar physical properties (KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) pg 14) .

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 7, 19-23, 26, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trau et al. in view of Hodak et al. (Langmuir, 1997).

These claims are to a battery comprising:

- An electrolyte suspension comprising plurality of hollow particles;
- These hollow particles entrap and oxidase enzyme, specifically **glucose oxidase (GOX)**;
- These hollow particles comprise an outer shell that is electrically conductive and permeable to the enzyme substrate;
- The particles have electron carriers comprising ferrocene and viologen derivatives.

As mentioned above, these claims have a series of intended uses as follows:

- The battery is for use in combination with a microchip;
- The electrolyte suspension can be used to generate a current of electrons.

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These intended uses and do not impart a structural relationship, such as an additional component, to this composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these intended uses are afforded little patentable weight.

Also the term “battery” is not explicitly defined in the specification. While the Applicant appears to mean “battery” as the galvanic cell of figure 1, the common use of the term “battery” is far broader. Merriam Webster online defines battery in the electrical sense as “a combination of apparatus for producing a single electrical effect” or “a single cell that furnishes electric current”. Therefore in the broadest but reasonable terms a battery is any apparatus or composition that generates an electric current or produces a single electrical effect. Prior Art reading on such an apparatus or composition will read on these limitations.

Trau et al. teach glucose oxidase entrapped in hollow particles with outer shells comprising polyelectrolytes (Fig 1, and Fig 2B) such as **polyallylamine-HCl (PAH)**, **poly-(sodium-4-styrenesulfonate) (PSS)** and **polyacrylic acid (PAA)** (pg 1493, Section 2.1). These particles are embedded in an electrically conductive matrix such as a platinum/carbon electrode or a gel-like membrane (Figs 2B and C and Fig 5). Trau et al. teach that these particles generate a current upon addition of glucose (Fig 7) and thus meet the broad definition of battery.

Since these materials are classified as electrolytes they are inherently electrically conductive as supported by Merriam Webster Online (“electrolyte”, Definition 1). Furthermore the outer shells of these hollow particles made from these polyelectrolytes inherently have conductivity and substrate permeability as indicated by the current generated when glucose is added to these hollow particles entrapping GOX (Fig 7). If these hollow particles were not inherently permeable to glucose then no current would be generated by the GOX for lack of

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substrate. If these hollow particles were not electrically conductive then they would insulate the GOX and prevent current flow. Both of these scenarios are unlikely given the substantial current flow over the control shown in Fig 7 that is a direct result of glucose addition.

What Trau et al. do not teach that the electrolyte comprises carriers such as ferrocene derivatives. Regardless this would have been obvious to one of ordinary skill in the art from the teachings of Hodak et al. They also teach that GOX encapsulated in a matrix of poly-allylamine, which is the same polyelectrolyte as Trau et al., but they teach that their poly-allylamine is derivatized with ferrocene (Hodak, Abstract and Fig 1). Hodak et al. teach that such derivatization provides “effective electrochemical communication” (Hodak, pg 2716) between the layers. Therefore it would have been obvious to one of ordinary skill in the art to apply the known technique of derivitizing poly-allylamine with ferrocene to the poly-allylamine capsules of Trau et al., since this is simply applying a known technique to the same polymer/enzyme system to improve electrochemical communication between the components ((KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) pg 13).

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowable or free of the art.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted

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that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Irene Marx/
Primary Examiner
Art Unit 1651